

submitting copies of each cited reference and a list of those references. Applicants note that "once the minimum requirements of 37 CFR 1.97 and 37 CFR 1.98 are met, the examiner has an obligation to consider the information." (MPEP 609).

Applicants thank the Examiner for returning the initialed PTO Form 1449 submitted on November 5, 2001. Information Disclosure Statements and accompanying PTO Forms 1449 also were transmitted to the Patent Office on February 26, 2001, and on June 22, 2001. Applicants request initialed copies of those PTO Forms 1449 to indicate that the references provided therein have been considered.

**35 U.S.C. §102**

MPEP 2131 quotes Verdegaal Brothers v. Union Oil of California, 814 F.2d 628, 631 (Fed. Cir. 1987) for the legal standard of anticipation: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (emphasis added).

RECEIVED  
AUG 30 2002  
TECHNOLOGY CENTER R3700

**Claims 1-7**

Applicants respectfully traverse this rejection. Claim 1 claims, among other things, "a device body formed of a superelastic or pseudoelastic material, the body having an insertion configuration and a tissue holding configuration in which the body has an inner flange and an outer flange, wherein at least one of the inner and outer flanges is radially constrained in the insertion configuration."

In contrast, Sakura neither teaches nor suggests an anastomosis device having a tissue holding configuration in which the body has an inner flange and an outer flange. The device 10 of Sakura is cylindrical, being formed from "a continuous filament 11 of resilient dental wire which generally runs in an "S"-pattern about the circumference of a cylinder." (column

3, lines 53-56; *see* column 2, lines 56-58). The device 10 of Sakura is cylindrical when holding tissue, because it returns to its original uncompressed size when compression is released. (*e.g.*, Figure 9; column 4, lines 31-35; column 5, lines 8-14). In the tissue holding configuration of Figure 9, there is no structure extending from the cylindrical body of the device 10 that can be characterized as a flange, much less structures corresponding to both an inner flange and an outer flange. Rather, the device 10 of Sakura is cylindrical along its entire length in a tissue holding configuration.

Further, the barbs 12, 13 extending from the device 10 of Sakura cannot be characterized as individual flanges, or as collectively forming a flange. Rather, the barbs 12 simply penetrate completely through the tissue of the graft vessel wall and of the target vessel wall in order to securely hold them together. That is, the barbs 12 do not form two flanges between which the tissue of the graft vessel wall and the tissue of the target vessel wall are compressed; rather, the barbs penetrate completely through the tissue of both the graft vessel wall and the target vessel wall in order to hold the two vessels together. (*e.g.*, Figures 8, 9).

Even if the barbs 12 could be characterized as forming a flange, which Applicants do not admit, the barbs 12 would form a single flange extending outward from the device 10, not both an inner flange and an outer flange. The two posts 13 cannot fairly be characterized as forming a flange, because they are simply two short stubs that extend outward in opposed directions to interface with a snare loop 20. (*e.g.*, Figures 1, 2; column 4, lines 2-7). Thus, each and every element in claim 1 is not found in Sakura, and Applicants believe that claim 1 is in condition for allowance.

Claims 2-7 depend directly or indirectly from claim 1, and are thus believed to be in condition for allowance as well.

#### Claims 8-13

Applicants respectfully traverse this rejection. Claim 8 claims, among other things, “a deployment tube; and an anastomosis device formed of a superelastic or pseudoelastic material, the device having an insertion configuration and a tissue holding configuration in which the device has an inner flange and an outer flange, wherein the inner and outer flanges are radially constrained in the deployment tube in the insertion configuration.”

As discussed above with regard to claims 1-7, Sakura neither teaches nor suggests an anastomosis device having a tissue holding configuration in which the device has an inner flange and an outer flange.

Further, Sakura neither teaches nor suggests a deployment tube. Instead, Sakura discloses a snare loop 20, which includes a line 21 that is wrapped around the device 10 to compress it. (e.g., Figures 3-6; column 4, lines 46-54). Thus, the device 10 is constrained by the line 21 for insertion into the end of a target vessel. At no time is the device 10 of Sakura radially constrained in a tube, in an insertion configuration or not. Thus, each and every element in claim 8 is not found in Sakura. Applicants believe that claim 8 is in condition for allowance.

Claims 9-13 depend directly or indirectly from claim 8, and are thus believed to be in condition for allowance as well.

#### Claims 14-19

Applicants respectfully traverse this rejection. Claim 14 claims, among other things, deploying the one piece device by self deformation to a tissue holding configuration in which the device has an inner flange and an outer flange and traps the target vessel tissue between the inner flange and the outer flange.

As discussed above with regard to claims 1-7, Sakura neither teaches nor suggests an anastomosis device having a tissue holding configuration in which the device has an inner flange and an outer flange.

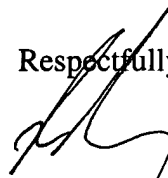
Further, Sakura neither teaches nor suggests trapping the target vessel tissue between an inner flange and an outer flange. Instead, the two vessels are held together by barbs that penetrate completely through the tissue of both the graft vessel wall and the target vessel wall. (e.g., Figures 8, 9). Thus, each and every element in amended claim 14 is not found in Sakura, and Applicants believe that claim 14 is in condition for allowance.

Claims 15-19 depend directly or indirectly from claim 14, and are thus believed to be in condition for allowance as well.

**REQUEST FOR ALLOWANCE**

Allowance of the pending claims is respectfully solicited. Please contact the undersigned if there are any questions.

Respectfully submitted,



Brian A. Schar  
Attorney for Applicants  
Reg. No. 45,076  
Tel. No. (650) 326-5600 x162  
Chief Patent Counsel  
Cardica, Inc.